

## **REMARKS**

In view of the above amendments and the following remarks, reconsideration of this application is respectfully requested.

### **Status of the Claims**

Upon entry of the amendments presented herein, claims 1-4 and 6-9 will be pending. Claims 5 and 10-15 are hereby canceled without prejudice.

The cancellation of claims 5 and 10-15 are being made by applicants solely for the purpose of advancing prosecution toward allowance, and are not to be construed as applicants' acquiescence to the appropriateness or validity of any of the currently pending claim rejections. Applicants reserve the right to pursue the canceled subject matter in one or more related applications.

### **Objection to the Specification/Abstract**

The objection to the "Abstract" is respectfully traversed in view of the above amendments to the Abstract and the submission herewith of the Abstract on a separate sheet. The amendments to the Abstract were necessary to correct an inadvertent typographical error. No new matter has been added by way of this amendment.

### **Rejection Under 35 U.S.C. § 112, First Paragraph—Enablement**

Claim 12 is rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. This rejection is respectfully traversed and rendered moot in view of the cancellation of claim 12.

Therefore, applicants respectfully submit that this rejection is improper and should be withdrawn.

### **Rejection Under 35 U.S.C. § 112, First Paragraph—Written Description**

Claims 5 and 12 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. This rejection is respectfully traversed and rendered moot in view of the cancellation of claims 5 and 12.

Therefore, applicants respectfully submit that this rejection is improper and should be withdrawn.

### **Rejection Under 35 U.S.C. § 112, Second Paragraph—Indefiniteness**

Claims 4, 6, and 9 are rejected under 35 U.S.C. § 112, 2nd paragraph, for alleged indefiniteness. As set forth below, applicants respectfully assert that this rejection is improper.

The Examiner argues that the term “substantially,” as used in the phrase “substantially removing” of rejected claims 4, 6, and 9, is a relative term that is not defined in the specification, and therefore renders the rejected claims indefinite. The Examiner provides no further arguments or reasoning to support this rejection, except to allege that the term “substantially” is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicants respectfully disagree and traverse this rejection.

The Manual of Patent Examining Procedure (MPEP) recognizes the term “substantially” as being an appropriate term for use in patent claims. *See* MPEP § 2173.05(b). In the context of alleged indefiniteness, the MPEP states the following:

The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

MPEP § 2173.05(b).

The MPEP specifically addresses the use of the term “substantially.” In particular, the MPEP recognizes that the term “substantially” is commonly used in patent claims “in conjunction with another term to describe a particular characteristic of the claimed invention.” MPEP § 2173.05(b)(D).

Federal patent case law also supports the use of the term “substantially” in patent claims. For example, the U.S. Court of Customs and Patent Appeals (CCPA) ruled that the limitation “to *substantially increase* the efficiency of the compound as a copper extractant” was definite in view of the general guidelines contained in the specification. *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975) (emphasis added). More recently, the Federal Circuit ruled that the limitation “which produces *substantially equal* E and H plane illumination patterns” was definite on the ground that one of ordinary skill in the art would know what was meant by “substantially equal.” *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988) (emphasis added). The Federal Circuit has also recognized that the term “substantially”—e.g., as used in the phrase “substantially equal”—can be appropriate in patent claims, even if some experimentation may be needed. *See Seattle Box Co. v. Industrial Crating & Packing*, 731 F.2d 818, 826, 221 USPQ 568, 573-574 (Fed. Cir. 1984) (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851, 105 S. Ct. 172, 83 L.Ed.2d 107 (1984)).

As noted by the Federal Circuit in the *Andrew Corp.* case, terms such as the relative term “substantially” (e.g., substantially equal) are “ubiquitous in patent claims.” *See id.* at 821. By conducting a patent claim search, applicants have confirmed the Federal Circuit’s conclusion with regard to the common use of the term “substantially” in patent claims, particularly regarding the use of the term “substantially removing” (or the like). More specifically, based on a simple search of the U.S. patent database (of patents issued since 1976), the terms “substantially removing,” “substantially remove,” “removing substantially,” or “remove substantially” appear in the claims of 5,096 issued patents. This search was conducted on August 3, 2009. Based on the number of patents alone, it is quite clear that the term “substantially removing” (or the like) is frequently recited in claims that are deemed to be allowable.

Applicants have selected just a small number of patents to show the common use of the term “substantially removing” (or the like). To this end, applicants respectfully direct the Examiner’s attention to Table 1, as set forth below.

**Table 1**

**Selected U.S. Patents Having Claims with the Term “Substantially Removing” (or the Like)**

<b>U.S. Patent</b>	<b>Claim</b>	<b>Element</b>
7,563,807	1	a step of contacting an untreated solution of the compound represented by Formula (I) with a reactive resin effective to <b><u>substantially remove</u></b> the aldehyde represented by Formula (II) from said untreated solution to form the clean solution
	6	said method comprising the step of contacting an untreated solution of the compound represented by Formula (Ia) with a polystyrene-based sulfonylhydrazine reactive resin effective to <b><u>substantially remove</u></b> the aldehyde represented by Formula (IIa) from said untreated solution to form said clean solution
7,563,430	2 & 12	<b><u>removing substantially</u></b> all of the solvent to form the hydrazine-based inorganic metal chalcogen cluster single source precursor
7,550,249	3	baking the substrate to <b><u>substantially remove</u></b> the solvent
	6	heating the photoresist coating to <b><u>substantially remove</u></b> solvent from the coating
7,544,500	1	<b><u>substantially removing</u></b> the plasminogen activator from the active plasmin by binding the active plasmin to an active plasmin-specific absorbent material to form a bound plasmin
7,534,910	6	wherein the partial pressure of alkene in the reaction zone is reduced by <b><u>removing substantially</u></b> all the alkene from the reaction zone
7,220,872	39	further comprising the step of <b><u>removing substantially</u></b> all of the transition metal or transition metal by-products by complexation, precipitation, filtration, centrifugation, electrochemical methodology, chromatography, chelation or any combination thereof

Here, applicants respectfully assert that, in view of the specification, one of ordinary skill in the art would readily understand the meaning of the term “substantially,” as recited in claims 4, 6, and 9. In the claims, the term “substantially” is recited as part of the step of “performing a saponification,” as follows (emphasis added):

- Claim 4(b): “***performing a saponification substantially removing* acyl groups,  $-\text{CH}_3(\text{CH}_2)_N\text{CO}$ , and the cetyltrimethyl ammonium salt groups, -CTA, from the hyaluronan (HA) ester to produce a regenerated HA”**
- Claim 6(b): “further comprising the step of ***performing a saponification substantially removing* acyl groups and the cetyltrimethyl ammonium salt groups, from the hyaluronan (HA) ester to produce a regenerated HA”**
- Claim 9(b): “***performing a saponification substantially removing* acyl groups and the cetyltrimethyl ammonium salt groups, from the hyaluronan (HA) ester to produce a regenerated HA”**

In light of the present specification, one of ordinary skill in the art would have no difficulty in understanding the meaning of the term “substantially removing” as recited in claims 4, 6, and 9. “Saponification” is a type of reaction that is well known by those of ordinary skill in the art. As noted, each of the rejected claims clearly states that the “substantially removing” aspect relates to the “saponification” step. The claims also state that performing the saponification step produces a regenerated hyaluronan (HA). Further, the claims expressly state what is being substantially removed in the saponification step, i.e., the acyl groups,  $-\text{CH}_3(\text{CH}_2)_N\text{CO}$ , and the cetyltrimethyl ammonium salt groups, -CTA, are being substantially removed from the hyaluronan (HA) ester to produce a regenerated HA.

The specification provides ample guidance for one of ordinary skill in the art to perform the saponification step (*see, e.g.*, Specification, at page 9, lines 4-16; page 13, lines 6-16; page 14, lines 22-31; and page 15, lines 34-36).

In view of the above, applicants respectfully submit that the term “substantially,” as used in claims 4, 6, and 9, is clear and unambiguous. Moreover, in light of the specification and knowledge that is well-known in the art, one of ordinary skill in the art would readily understand the meaning and scope of the term “substantially,” as used in the claims.

Accordingly, applicants respectfully submit that claims 4, 6, and 9 are not indefinite, and respectfully request reconsideration and withdrawal of the present rejection under 35 U.S.C. §112, second paragraph.

#### **Rejection Under 35 U.S.C. § 102(b)**

Claims 12-15 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,644,049 to Giusti et al. (“Giusti”). This rejection is respectfully traversed and rendered moot in view of the cancellation of claims 12-15.

Therefore, applicants respectfully submit that this rejection is improper and should be withdrawn.

#### **Rejection Under 35 U.S.C. § 103(a)**

Claims 10-15 are rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Giusti in view of U.S. Patent No. 4,851,521 to della Valle et al. (“della Valle”). This rejection is respectfully traversed and rendered moot in view of the cancellation of claims 10-15.

Therefore, applicants respectfully submit that this rejection is improper and should be withdrawn.

### **CONCLUSION**

Claims 1-4 and 6-9 are now under consideration in this case. In view of the foregoing, applicants respectfully submit that the claims of the present application are in condition for allowance and such allowance is earnestly solicited.

If any unresolved issues remain that might prevent the prompt allowance of the present application, the Examiner is respectfully encouraged to contact the undersigned at the telephone number listed below to discuss these issues.

Submitted herewith via EFS-Web is payment for a one-month extension of time under 37 C.F.R. § 1.17(a)(1) (\$65.00, Small Entity). The Commissioner is hereby authorized to charge any fees that may have been overlooked, or to credit any overpayments of fees, to Deposit Account No. 08-1935.

Respectfully submitted,

HESLIN ROTHENBERG FARLEY & MESITI P.C.

By: **/Andrew K. Gonsalves/**

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